# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**
**No. 21-2286V**

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| CINDY OVERTON,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Chief Special Master Corcoran<br><br>Filed: March 20, 2024 |

*John Robert Howie, Howie Law, PC, Dallas, TX, for Petitioner.*

*Voris Edward Johnson, U.S. Department of Justice, Washington, DC, for Respondent.*

**RULING ON ENTITLEMENT – SPECIAL PROCESSING UNIT**[1]

On December 13, 2021, Cindy Overton filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her on November 10, 2020. Petition (ECF No. 1); *see also* Amended Petition filed May 19, 2022 (ECF No. 10). The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the foregoing reasons, I find that Petitioner has established by preponderant evidence that her pain and limited range of motion were limited to the vaccinated shoulder. Based on the lack of other objection from Respondent and an independent review of the record, Petitioner has established entitlement for a Table SIRVA.

## I. Procedural History

The case was assigned to SPU in July 2022. ECF No. 21. In May 2023, while Respondent's medical review of the case was still pending, I denied Petitioner's request to retain vocational and economic experts to help formulate her demand. ECF Nos. 31 – 32, 35. Then in July 2023, Respondent invited settlement discussions. ECF No. 38. But because Petitioner maintained that experts were necessary to prepare any demand and the case had been pending in SPU for over a year, I determined that adjudication of the Table SIRVA claim was appropriate. ECF Nos. 39 – 40.[3] Accordingly on October 10, 2023, Respondent duly filed the Rule 4(c) Report (ECF No. 43), which was followed by sequential briefing. Petitioner's Brief filed on Dec. 1, 2023 (ECF No. 44);[4] Respondent's Response filed on December 14, 2023 (ECF No. 46); Petitioner's Reply filed on December 29, 2023 (ECF No. 47). The matter is ripe for adjudication.

## II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

[3] Respondent did not oppose Petitioner's early requests to retain "damages" experts, *See* ECF Nos. 31, 39, and suggests that the lack of authorizing such experts "effectively shu[t] down the possibility of settlement," Response at 2. But special masters have responsibility and discretion in determining what proceedings are appropriate. *See* Vaccine Rule 3. Moreover, experts are not encouraged in SPU generally – even less so before entitlement has been formally decided, and I did not see good reason to authorize them here.

[4] Petitioner styled the filing as a "Motion to Strike Respondent's Rule 4(c) Report or, Alternatively, Motion to Compel A More Detailed Rule 4(c) Report." But it set forth Petitioner's analysis of her case, and citations to past SPU cases, regarding the sole disputed requirement for the alleged Table SIRVA. Therefore, I denied the request for relief, in favor of Respondent filing a Response and then Petitioner filing any Reply. Scheduling Order filed Dec. 4, 2023 (ECF No. 45).

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[5] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would

[5] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

> not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

## III. Relevant Evidence

I have reviewed all submitted evidence including all medical records and affidavits, as well as the Petition (as amended), the Rule 4(c) Report, and both parties' briefing. The following section focuses on the evidence most relevant to the disputed criterion.

- Petitioner received the subject intramuscular flu vaccine in her left deltoid on November 10, 2020. Ex. 2 at 1 – 2.[6] The vaccination was mandated by her nursing job. Ex. 1 at ¶ 2. She was 40 years old, with a history of chronic neck and back pain, but no apparent musculoskeletal issues with her left shoulder. Rule 4(c) Report at 2 (citing Ex. 8a at 110 – 16; Ex. 9a at 406 – 07; Ex. 10 at 38 – 40, 236 – 37).

[6] Petitioner's employer did not provide any contemporaneous record of the site of vaccine administration, despite repeated efforts by her counsel. *See* Amended Petition at n. 2. However, Respondent states that the vaccine was administered in her left deltoid, Rule 4(c) Report at 2, and I agree that the preponderance of available evidence supports a left-sided administration.

- One day after vaccination, on November 11, 2020, Petitioner presented to an emergency room ("ER"), and a triage nurse recorded the chief complaint of "pain to left shoulder after flu shot," currently rating 7/10. Ex. 10 at 300, 302. Afterwards, a physician incorrectly recorded a *right*[7] shoulder injury. *Id.* at 298. The physician also recorded that Petitioner's vaccination was followed by "mild pain… progressively worsened and now she has limited ROM, tingling in her fingers and arm pain." *Id.* The same physician's objective physical examination was focused on the musculoskeletal system of the shoulder – revealing tenderness and range of motion limited by pain. *Id.* at 299. His differential diagnosis was a contusion, sprain, rotator cuff injury, or other shoulder pain. *Id.* Petitioner also received patient education materials regarding seroma, defined as "a sterile collection of fluid under the skin, usually at the site of a surgical incision." *Id.* at 306 - 07. She was told to perform ROM exercises, use a heating pad, and follow up with her primary care provider ("PCP") unless she needed further emergency attention. *Id.* at 299, 304.

- Next, on November 18, 2020, at her workplace's occupational health clinic, a physician evaluated Petitioner's chief complaint of "left shoulder pain down to arm after flu vaccine." Ex. 9b at 2. The injury had "started with pain at local injection site that eventually affected entire arm… [Petitioner] was better but still with significant issues using arm because of pain." *Id.* at 4. The pain rated 3/10, involved limited range of motion and tingling but did not involve itching, joint locking, joint swelling, numbness, or stiffness. *Id*. The exam found injection site tenderness; and nearly full ROM but pain past 90 degrees flexion and abduction of the shoulder. The assessment was a "a local reaction to poor injection technique." *Id.* at 9. Petitioner was given ROM exercises and told to return to work with restrictions. *Id.*

- Later on November 18, 2020, in a patient portal message to her PCP, Petitioner reported that her vaccination had caused "decreased ROM, pain, with numbness and tingling in my fingers." Ex. 8c at 261. Petitioner asked whether "gabapentin would help with the nerve pain." *Id.* That same day, the PCP wrote a prescription for gabapentin – without any evaluation or response to Petitioner). Ex. 8d at 47.

- On November 23, 2020, Petitioner messaged her PCP again, reporting "pain, numbness, and tingling that radiates down into my fingers, and decreased range of motion in my left shoulder/arm immediately following an influenza vaccine which seemed to cause a damaging reaction in my joint." Ex. 8c at 261. Petitioner also reported continued "pain while abducting and rotating my arm." *Id.* Because gabapentin (prescribed five days earlier) had not made "a significant difference in

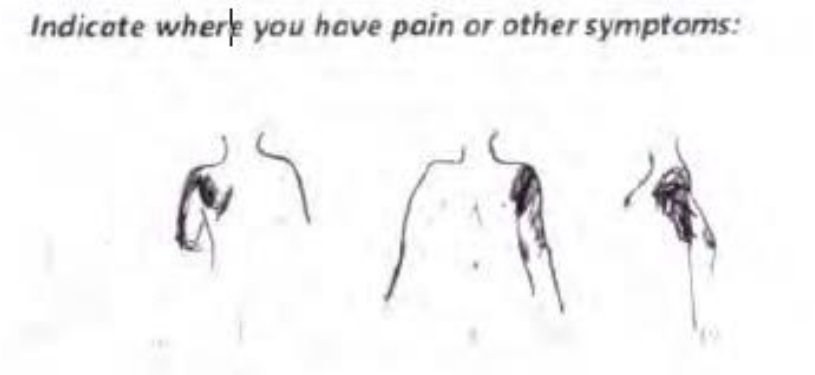
[7] The parties agree that any references to Petitioner experiencing a right-sided injury are incorrect. Amended Petition at n. 3; Rule 4(c) Report at n. 2.

pain," she asked whether "an IM dexamethasone injection (not in [her] deltoids) would help [her] heal sooner." *Id.* The PCP did not offer that treatment, evaluate, or respond to Petitioner.[8]

- On November 30, 2020, Petitioner presented to the same ER, where a nurse recorded a chief complaint and exam findings of left shoulder pain increased with movement, specifically on abduction. Ex. 9b at 49, 51. The assessment was rotator cuff tendinitis or tendinopathy, to be treated with increased gabapentin, as well as baclofen and NSAIDs. *Id.* at 52.

- At a December 2, 2020, occupational health re-evaluation, Petitioner reported that she had found a better sleep position which helped to manage the pain at night, but the pain was still preventing use of her left arm especially with reaching. Ex. 9b at 85. The exam found decreased abduction (80 degrees) and mildly decreased internal and external rotation. *Id.* at 89. The physician suspected that the flu shot "may have been put in or near a rotator cuff tendon," and referred Petitioner to physical therapy ("PT"). Ex. 9b at 89; *see also id.* at 131 - 35.

- Upon starting PT on January 19, 2021,[9] Petitioner characterized her injury as "severe left shoulder and arm pain with decreased ROM, increased pain at night and with abduction" – as illustrated below:




Ex. 12 at 10. The therapist's exam and assessment were of left shoulder pain and dysfunction. *Id.* at 6 – 7. Petitioner attended six PT visits concluding on February 9, 2021. *Id.* at 8 – 40.

[8] Petitioner subsequently requested refills of medications including gabapentin and acetaminophen-codeine (initially prescribed for a preexisting complaint), which the PCP granted. Ex. 8c at 259 – 260; Ex. 8d at 32 – 46. But the PCP did not *evaluate* her alleged vaccine injury or any other complaint until over two months post-vaccination, on January 14, 2021, via telehealth. Ex. 8a at 14 – 22.

[9] PT was delayed because Petitioner contracted an upper respiratory infection and then COVID, *see* Ex. 8b at 1 – 6; Ex. 8c at 258 – 60.

- At a February 10, 2021, occupational health re-evaluation, Petitioner reported that her left shoulder pain was "much better" with PT but was recently strained when she was putting a half-gallon of fluid into the refrigerator. Ex. 9b at 177. After assessing that her chronic left shoulder pain was "slow to resolve," *id.*, the physician ordered an MRI which revealed a supraspinatus tendon tear, and edema in the superior deltoid and posterior aspect of the humeral head. *Id.* at 233.

- At a March 3, 2021, initial evaluation with a sports medicine physician, Petitioner reported that the flu vaccine was administered "really high up on her deltoid" and had caused significant pain in the anterior, superior, and lateral portions of her shoulder… worsened by any motion." Ex. 9b at 230. An exam found acromion tenderness, limited abduction, and a positive Hawkins test. *Id.* at 232. The sports medicine physician's assessment was a supraspinatus tear. *Id.* at 233. Petitioner deferred an injection for pain relief to avoid affecting the timeline for a possible surgery. *Id.*

- On March 8, 2021, an orthopedic surgeon concurred that the supraspinatus tear was "right in line with the edema where the shot was given." Ex. 9b at 285. He planned arthroscopic surgery – likely consisting of a rotator cuff repair with subacromial decompression. *Id.* But the orthopedic surgeon cautioned that "surgery may only help cuff tear pain," and would "not take care of the pain in the deltoid from the shot." *Id.*[10]

- On March 26, 2021, the orthopedic surgeon performed the surgery as planned. Ex. 9c at 13 – 15. He did not change his assessment of the injury at that time or at post-operative evaluations. Ex. 9c at 198 – 99; Ex. 15 at 6 - 7, 58 – 60, 102; *accord* Ex. 15 at 114 – 18 (occupational health follow-up similarly noting assessment of a supraspinatus tear).

- Between April – September 2021, Petitioner attended 30 post-operative PT sessions, which were focused on ongoing left shoulder pain and dysfunction. Ex. 9c at 246 – 47; Ex. 12 at 41 – 73; Ex. 21; Ex. 22 at 1 - 52.

- On October 11, 2021, the orthopedic surgeon recorded that Petitioner's pain had recently "flared," and an exam found new subacromial crepitus with range of motion, which was concerning for calcific tendinitis. Ex. 15 at 161 – 64.

[10] The orthopedic surgeon also secured Petitioner's consent for potential submission of her case in medical literature. Ex. 9b at 286. One week later, either the orthopedic surgeon or Petitioner submitted a VAERS report. *Id.* at 332; Ex. 13.

- On November 1, 2021, the orthopedic surgeon reviewed that a repeat MRI showed that "the rotator cuff tear where the tendon had pulled off the bone is well healed." Ex. 15 at 257; *see also* Ex. 17 at 7 – 8 (MRI report). The orthopedic surgeon assessed that Petitioner's ongoing issues were "still from the damage to the muscle tendon area from the flu shot injection." Ex. 15 at 257. The damage was "likely in an area that is not repairable," although he planned a second arthroscopic surgery to check for any issues or additional pathology. *Id.*

- That second arthroscopic surgery, occurring on December 17, 2021, consisted of subacromial decompression and a rotator cuff repair/ dermal patch application. Ex. 15 at 438. It did not change the orthopedic surgeon's assessment or reveal any additional findings. *Id.*; *see also* Ex. 15 at 612, Ex. 16 at 621 – 22, 713 – 15.

- Between January – April 2022, Petitioner attended another course of post-operative PT consisting of about 20 sessions. Ex. 22 at 103 – 58. She also followed up with the occupational health physician. Ex. 15 at 652 – 57; Ex. 16 at 664 – 69, 776 – 72. These records are also focused on a left shoulder injury.

- Subsequent medical records document ongoing shoulder issues, but are not relevant to the question of entitlement to compensation. Rule 4(c) Report at 6.

## IV. Analysis

The third QAI requirement for a Table SIRVA is what the parties dispute herein has been satisfied. It requires that a petitioner's "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii). Respondent argues that "when Petitioner *initially* sought treatment for the alleged SIRVA, she reported pain and tingling that radiated into her arm and hand." Rule 4(c) at 7 (citing Ex. 10 at 298; Ex. 9b at 2 – 9; Ex. 8c at 261) (emphasis added).

Those reports reasonably introduce a *question* about whether this element is met. But Petitioner's report one day post-vaccination at an ER, was of both "shoulder pain" and "arm pain." There is no further detail about the pain's location, and it also appears alongside the undisputedly incorrect notation of the injury being right-sided – somewhat weakening the presumption of accuracy for that record overall. Ex. 10 at 298.

Petitioner's other reports within that initial timeframe can reasonably be understood to reflect complaints of pain in her shoulder that extended down the arm, particularly upon movement of the shoulder. The pain at this point had not been alleviated by any medication or treatment. Two of the descriptions appear within patient portal messages, without any evaluation or recorded response from her PCP that might have informed the

analysis. Ex. 8c at 261. And Petitioner's fourth and last report of pain potentially extending beyond her arm was *not* corroborated by the occupational health physician's exam and assessment, which were limited to the shoulder. Ex. 9b at 2 – 9. Thus, these notations are not strong evidence of non-shoulder pain.

Crucially, 42 C.F.R. § 100.3(c)(10)(iii), like any Table requirement or other key pleading, must be resolved by a preponderance of the *entire* evidentiary record. Sections 11(c)(1), 13(a)(1)(A). Respondent's analysis is unduly focused on just a few initial notations. In contrast, the medical records for at least one and a half years post-vaccination consistently reflect complaints of pain in the shoulder and deltoid muscle. At most, that pain extended into the upper am (as does the deltoid muscle), but certainly stopped above the elbow. *See, e.g.*, Ex. 12 at 10 (illustration on PT new patient questionnaire, replicated above). The objective examination findings were even more consistent in documenting pain limited to the left shoulder and the overlying deltoid muscle in which the vaccine was administered.

It is also undisputed that Petitioner developed objectively reduced range of motion that was limited to the shoulder (e.g., without any motion limitations of say, her elbow or wrist). And Petitioner correctly notes that 42 C.F.R. § 100.3(c)(10)(iii) does not speak to the presence or absence of any other symptoms *beyond* pain and limited range of motion. Reply at 5 – 7.[11,] Therefore, preponderant evidence supports the conclusion that the plain language of this requirement has been met.[12]

[11] In an appropriate case, the existence of additional symptoms such as numbness and tingling *may* constitute clinical evidence of another condition, potentially neurological in nature, that would explain the patient's symptoms under 42 C.F.R. § 100.3(c)(10). But that possibility was not raised by any treating providers or by Respondent in this case. Rule 4(c) Report at n. 4. And of course here, any complaints not obviously falling within the understanding of SIRVA (e.g., numbness, tingling) should not be factored into the award of damages for SIRVA.

[12] *Accord, e.g.*, *Werning v. Sec'y of Health & Hum. Servs.*, No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding "preponderant evidence in her medical and treatment records to find that [the petitioner's] pain and limited range of motion was limited range of motion was limited to her right shoulder"); *K.P. v. Sec'y of Health & Hum. Servs.*, No. 19-0065V, 2022 WL 3226776, at *7 (Fed. Cl. Spec. Mstr. May 25, 2022) (finding that "the weight of the evidence is limited to the relevant area (the shoulder), even if initially Petitioner reported other pain [which…] was never subsequently corroborated"); *Cross* v. Sec'y of Health & Hum. Servs., No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Dec. 2, 2022) ("[C]laims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table").

Both parties also referenced Respondent's *underlying concerns* motivating the establishment of this particular SIRVA element.[13] Those are also satisfied by the case-specific evidence – given that the treating providers consistently assessed Petitioner with a musculoskeletal injury, specifically to the deltoid muscle and supraspinatus tendon, which was caused by the vaccine's injection. *See, e.g.*, Ex. 9b at 285; Ex. 15 at 257. This evidence only strengthens Petitioner's position on the disputed issue.

## Conclusion

For the foregoing reasons, a preponderance of the evidence establishes 42 C.F.R. § 100.3(c)(10)(iii). All other QAI criteria are met, as is the six-month severity requirement. *See* Rule 4(c) Report at n. 4. Accordingly, Petitioner has established entitlement for a Table SIRVA. An order setting next deadlines for the case's damages phase will follow.

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**
Brian H. Corcoran
Chief Special Master

[13] Brief at 6 – 7 and Response at 5 – 6, citing:

> Comment: A commenter suggested that shoulder injury related to vaccine administration (SIRVA) as defined in the QAI is too restrictive because the recipient's pain and reduced range of motion must be limited to the shoulder in which the intramuscular vaccine was administered. The commenter stated that such language was an artificial and unnecessary qualification, and expressed concern that recipients who have other symptoms, such as shoulder pain radiating to the neck or upper back, will not have the benefits of a Table injury. The commenter suggested that the QAI be expanded to include the shoulder and parts of the body attributed to that injury.
>
> Response: SIRVA is a musculoskeletal condition caused by injection of a vaccine intended for intramuscular administration into the shoulder, and, as its name suggests, the condition is localized to the shoulder in which the vaccine was administered. In other words, pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA. Shoulder injuries that are not caused by injection occur frequently in the population. Thus, it is important to have a definition of SIRVA that is clearly associated with vaccine injection. The portion of the QAI limiting the pain and reduced range of motion to the shoulder in which the vaccine was administered is necessary to accurately reflect the vaccine-associated condition.

Notice of Proposed Rulemaking, 82 Fed. Reg. 6294-01 (Jan. 19, 2017).